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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/177,843	10/22/1998	JOHN LOIKE	48940-A-PCT-	3650

7590 10/03/2003

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NEW YORK, NY 10036

EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1642	27

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/177,843	LOIKE ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-39 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-39 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed 7/15/2003 (paper no. 26) is acknowledged and entered into the record. Accordingly, claims 1-26, and 42-54 are canceled without prejudice or disclaimer.

2. Claims 27-39 and 41 are pending and examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

3. The rejection of claims 27-39, and 41 under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the instantly claimed invention can be practiced by one of skill in the art without undue experimentation. Applicant supports this assertion by paralleling the instantly claimed invention with the findings of the court decision *In re Wands*. In *Wands*, the invention was drawn to a method of immunoassaying HbsAg using high affinity monoclonal IgM antibodies. Applicant argues that close parallels can be made between both the instant case and that of *Wands* in that both "claim methods" (see page 9 last sentence of paper no. 26) and that "both employ the use of an antibody" (see page 10, line 1). Applicant's further argues that in both cases, the skilled artisan would rely on routine experimentation to find other antibodies to be used in the claimed methods. Applicant's arguments have been carefully considered but are not found persuasive. First, the instantly claimed invention is drawn to a method of treating a malignant tumor comprising the administration of an agent that binds to a β 1 integrin, of which an agent can be an antibody. The instantly claimed invention differs from that of *Wands* in that there is an additional step involved in the instant invention, namely, treatment. This

difference, accounts for the lack of monoclonal antibodies treatments, in general, for the field of cancer immunotherapy. Furthermore, as stated in the prior office action, not all antibodies that recognize the β 1 integrin will be effective in treating, given the teachings of Seaver S *et al.* As such, routine experimentation would be burdensome to one of skill in the art, because the specification has not provided one of skill in the art with the necessary information to practice the claimed invention commensurate in scope to the claims.

Claim Rejections Maintained - 35 USC § 102

4. The rejection of claims 27, 28, 29 and 41 under 35 USC 102 (b) as being anticipated by Bourdon *et al* is maintained for the reasons of record. Applicant argues that the claims as currently amended would over come the art of record because the Bourdon *et al* do not specifically recite the types of leukocytes cells as recited in the claims. Applicant's arguments have been carefully considered but are not found persuasive. The method relies on the administration of an agent that binds to a β 1 integrin cell surface receptor, wherein the agent comprises an antibody, an antibody fragment, or a peptide comprising SEQ ID No: 2. The method taught by Bourdon *et al* would inherently perform the same function as that instantly claimed. Regardless of the type of cell treated, the administration of an antibody, antibody fragment, or peptide that binds to a β1 integrin receptor would inherently provide the same function and yield the same result as that instantly claimed. Bourdon *et al* taught that the administration of an antibody or peptide against the β1 integrin receptor modulated the attachment of cells to tenascin. The limitation of the claims to recite the specific type of leukocyte cells does

not preclude the instantly claimed invention from modulating/inhibiting the attachment of other cells to tenascin, as claimed by Bourdon *et al.*

Claim Rejections Maintained - 35 USC § 102

5. The rejection of claims 27, 28, 29 and 41 under 35 USC 102 (e) as being anticipated by Ruoslahti *et al* is maintained for the reasons of record. Applicant argues that the claims as currently amended would over come the art of record because the Ruoslathi *et al* do not specifically recite the types of leukocytes cells as recited in the claims. Applicant's arguments have been carefully considered but are not found persuasive. The method relies on the administration of an agent that binds to a β 1 integrin cell surface receptor, wherein the agent comprises an antibody, an antibody fragment, or a peptide comprising SEQ ID No: 2. The method taught by Ruoslahti *et al* would inherently perform the same function as that instantly claimed. Regardless of the type of cell treated, the administration of an antibody, antibody fragment, or peptide that binds to a β1 integrin receptor would inherently provide the same function and yield the same result as that instantly claimed. Ruoslathi *et al* taught that the administration of a peptide against the β1 integrin receptor modulated the attachment of cells to ECM. The limitation of the claims to recite the specific type of leukocyte cells does not preclude the instantly claimed invention from modulating/inhibiting the attachment of other cells to the ECM in general, as claimed by Ruoslathi *et al.*

All other rejections and or objections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 26.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Christopher Yaen
Art Unit 1642
September 29, 2003